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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,342	04/30/2001	George Jackowski	2132.026	3141

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EXAMINER
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ART UNIT	PAPER NUMBER
1641	14

DATE MAILED: 04/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/846,342	Applicant(s) JACKOWSKI ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *27-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7 & 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, claims 1-26 in Paper No. 13 is acknowledged.

2. Claims 27-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

3. This application contains claims drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

4. The use of a plurality of trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 2-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it is drawn to an intended use, which is not patentable.

Claims 3-5 are confusing because it is unclear what is being claimed. It appears that claim 3 is a method for detecting an analyte and comparing the detected analyte to a biopolymer marker having SEQ ID NO. 1; and claims 4 and 5 are methods for diagnosing a particular disease by detecting and comparing the detected biopolymer marker to SEQ ID NO. 1. However, the recitation of "evidencing and categorizing" is confusing because it is unclear how the detected biopolymer marker is evidenced or categorized? For example, what assay steps are involved in evidencing and categorizing. Claim 3 is further vague and indefinite because it is unclear how the detected biopolymer evidences and categorizes a disease state.

Claim 3 is also confusing because it appears that after mass spectrophotometric analysis is done on a sample, the mass of the biopolymer is obtained. From this, it is unclear how the mass of the biopolymer is correlated or compared to a biopolymer having SEQ ID. NO. 1. Is there a linear correlation? Or a correlation between the amino acid compositions of the detected biopolymer and those of SEQ ID NO. 1? It is further confusing because if the mass of two polypeptide is compared, it does not necessarily leads one to the same or similar sequence or even the same or similar protein. It is unclear what comprises "correlation". Would a 20% or 50% or 80% linear match be considered positive or negative or inclusive?

Claims 4 and 5 are vague and indefinite with respect to the recitation of "analytes thereof" because it is unclear what comprises analytes of a biopolymer marker.

Claims 10-26 are vague and indefinite because it is unclear what is being claimed. Furthermore, it is unclear what comprises "analyte thereof" of the biopolymer marker having SEQ ID NO. 1.

Claims 15, 16, 23 and 24 are vague and indefinite because a test "sample" cannot be considered part of an assay kit. Samples are collected at the time of the assay and not pre-packaged with the reagents of a kit.

Claim 26 is vague and indefinite because it is drawn to an intended use, which is not patentable.

Claim Rejections - 35 USC § 112, first paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

7. Claims 3-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7.1 Newly added claims 3-9 recite a method for evidencing and categorizing at least one disease state by detecting at least one biopolymer marker from a patient sample and comparing the detected biopolymer to the biopolymer marker having SEQ ID NO. 1. Correlation of the detected biopolymer marker to SEQ ID NO. 1 evidences and categorizes at least one disease state. Such a method is not supported by the specification as originally filed. The specification at pages 26-31 discloses how the biopolymer marker having SEQ ID NO. 1 was identified from patient serum samples, however, nowhere in the specification is there is teaching of detecting any other

biopolymer marker, comparing the detected marker to SEQ ID NO. 1, and determining a disease state from the detected marker. Furthermore, it is unclear exactly what "correlation" involves. Is there a limit to what would be considered a positive correlation, i.e. would a 50% match between the detected marker and SEQ ID NO. 1 considered positive or negative? There is no clear teaching of this in the specification or anywhere else. Applicant is required to cancel the new matter. In the event that Applicant believes support for the kit can be found in the specification, it is respectfully requested that Applicant points to the page and line number where such support may be found.

7.2 Newly added claims 10-26 recite a test kit comprising a binding partner for a biochemical marker, which includes a biopolymer marker having SEQ ID NO. 1, and means for determining the binding. Such a test kit is not supported by the specification as originally filed. The specification does not contain any discussion of a test kit comprising the reagents stated above. The specification at page 18, lines 5-7 recite a diagnostic kit for determining the presence of the disease specific marker having SEQ ID NO. 1, however, there is no recitation of what is in the kit, nor is there any discussion of what the binding partner for SEQ ID NO. 1 may be. Applicant is required to cancel the new matter. In the event that Applicant believes support for the kit can be found in the specification, it is respectfully requested that Applicant points to the page and line number where such support may be found.

8. Claims 3-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Claims 3-9 are directed to a method for evidencing and categorizing at least one disease state by detecting at least one biopolymer marker from a patient sample and comparing the detected biopolymer to the biopolymer marker having SEQ ID NO. 1. Correlation of the detected biopolymer marker to SEQ ID NO. 1 evidences and categorizes at least one disease state. Such a method has not been describe in the specification in such a way as to enable one skill in the art to make and use the invention as claimed. The specification states that a biopolymer marker having SEQ ID NO. 1 was found in serum samples of patients suffering from a variety of disease states (specification, page 26, lines 20-22), and this biopolymer marker is indicative of myocardial infarction, MI, (specification, page 27, lines 17-23.) However, the specification does not have any data supporting this assertion. Data presented in Figure 1 is not convincing, nor does it clearly demonstrate that SEQ ID NO. 1 is indicative of MI. A compound found in MI patients does not mean that the same compound is not present in normal or control subjects. Since the specification does not have any data for normal or control subjects, it would require undue experimentation for one skilled in the art to make and use the invention as claimed. The specification lacks proper guidance to enable one skill in the art to determine the incidence of disease as related to the presence or absence of a biopolymer that correspond to the

maker having SEQ ID NO. 1. The specification further lack proper guidance to enable one skilled in the art to distinguish between any and all disease states as claimed.

Because of the lack of description in the specification for the claimed method, it cannot be conclusively determined from the data presented in Figure 1 that anyone or everyone who has this polypeptide marker suffers from any diseases, specifically MI. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001. That requirement has not been met in this specification with respect to a method for evidencing and categorizing at least one disease state by detecting a biopolymer marker in a patient sample and comparing the detected biopolymer to a biopolymer marker having SEQ ID. NO. 1.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 09/846,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a biopolymer marker having a known sequence. SEQ ID NO. 1 of '780 encompasses the SEQ ID NO. 1 of the instant claims. In addition, both applications are also claiming a method for evidencing and characterizing a disease related to the biopolymer marker having SEQ ID NO. 1 and diagnostic kit for identifying the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 09/845,719. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEGGGVR (residues 5-15 of '719). SEQ ID NO. 1 of '719 encompasses the instantly claimed SEQ ID NO. 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 09/845,725. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEGGGVR (residues 2-12 of '725). SEQ ID NO. 1 of '725 encompasses the instantly claimed SEQ ID NO. 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 09/846,780. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to the sequence ID GDFLAEGGGVR (residues 6-16 of '780). SEQ ID NO. 1 of '780 encompasses the instantly claimed SEQ ID NO. 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nakamura et al., (J. Biochem. **94**. 1973-1978. 1983).

Nakamura discloses the sequences of the fibrinopeptide A (from residues 1-10) that encompasses the claimed SEQ ID. NO. 1. See Abstract.

Even though Nakamura does not teach that the peptide is indicative of a disease state, specifically MI, such an indication is seen as intended use and is not given patentable weight.

16. Claims 1-2 and 10-26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grieninger et al (USP 5,817,768).

Grieninger discloses fibrinogen protein and its' sequence as well as monospecific antibodies to different individual epitopes of the alpha subunit of fibrinogen. Grieninger teaches antibodies conjugated to detectable labels and solid substrate materials for use in convention assays to detect fibrinogen. See columns 4 and 5. Grieninger also teaches kits comprising anti-fibrinogen antibodies, means for detecting the binding in the form of labeled makers and substrate surfaces. See column 6, lines 17-26.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
April 24, 2003